

REMARKS

Status of the Claims.

Claims 1-4, 6-13, 16-18, 21-26, 71, 79, and 82-89 are pending with entry of this amendment, no claims being cancelled and no claims being added herein. Claims 1, 16, 71, and 79 are amended herein. These amendments introduce no new matter. Support is replete throughout the specification and claims as originally filed.

35 U.S.C. §112, First Paragraph, description requirement.

The rejection of claims 1, 4, 6-13, 21-26, 71, 79, and 82-85 under 35 U.S.C. §112, first paragraph, as allegedly overbroad because, according to the Examiner, it is not clear if the functional language "... encoding a transcription factor" is descriptive of SEQ ID NO:1 or descriptive of the claimed nucleic acid.

Claims 1 and 16 are amended herein in accordance with the Examiner's recommendation thereby obviating this rejection.

35 U.S.C. §102(e).

The rejection of claims 1, 2, 6-13, 21-26, 79, and 82-87 under 35 U.S.C. §102(e) as allegedly anticipated by Khola *et al.* (U.S. Patent 5,789,200). **Upon an indication of otherwise allowable subject matter, in accordance with MPEP §2308.01, Applicants will file a statement under 37 C.F.R. §1.6089(a).**

New Rejections:

35 U.S.C. §112, Second paragraph.

Claims 1, 4, 6-13, 16-18, 21-26, 71, 79, and 82-85 were rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite for the reasons listed below.

Claims 1 and 16 were rejected as allegedly indefinite because, according to the Examiner, it is not clear that the functional language "encodes a transcription factor that binds to and transactivates the rHer-2/neu Ets response element" is a description of SEQ ID NO:1 or a description

of the claimed nucleic acid. In accordance with the Examiner's recommendation, claims 1 and 16 are amended herein to recite "... wherein the nucleic acid encodes a transcription factor that binds to and transactivates the Her-2/neu Ets response element." thereby obviating this rejection.

Claims 1 and 16 were rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite because "... the same nucleic acid that hybridizes to the coding sequence, and is therefore, a non-coding sequence 'encodes a transcription factor'". In accordance with the Examiner's recommendation, claims 1 and 16 are amended to recite "... specifically hybridizes under stringent conditions comprising washes at 65°C in 0.2x SSC to the complement of a polynucleotide consisting of the sequence of SEQ ID NO: ...", thereby obviating this rejection.

Claims 1 and 16 were rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite because the claims use the term "nucleic acid" in reference to at least two different nucleic acids. In accordance with the Examiner's recommendation, claims 1 and 16 are amended to recite "... comprising washes at 65°C in 0.2 x SSC to a *polynucleotide* consisting of the sequence ... " thereby obviating this rejection.

Claim 79 was rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite because it is drawn to a kit for detection of an ESX gene or polypeptide, where the kit comprises nucleic acids. According to the Examiner, the specification fails to teach how nucleic acids may be used in a kit having the purpose of detecting a polypeptide.

Claim 79 is amended herein to recite "[a] kit for the detection of a ESX gene, said kit comprising. ... " thereby obviating this rejection.

Claim 79 was further rejected as indefinite because of the phrase "hybridizes under stringent conditions". Claim 79 is also amended herein to recite "... wherein said stringent conditions comprise 0.01 to 1.0 M sodium ion concentration (or other salts) at pH 7.0 to 8.3 and the temperature is 30°C." thereby obviating this rejection.

35 U.S.C. §102(b)

Boehringer Mannheim Biochemicals

Claim 79 was rejected under 35 U.S.C. §102(b) as allegedly anticipated by Boehringer Mannheim Biochemicals (1994 Catalog). According to the Examiner, Boehringer Mannheim teaches a

kit comprising a container of all possible hexanucleotides which would contain nucleic acids that would hybridize to a nucleic acid of claim 1. Applicants traverse.

Claim 79, and consequently its dependent claims, recites:

79. A kit for the detection of a ESX gene, said kit comprising a container containing a nucleic acid **that specifically hybridizes under stringent conditions to a nucleic acid of claim 1 wherein said stringent conditions comprise 0.01 to 1.0 M sodium ion concentration (or other salts) at pH 7.0 to 8.3 and the temperature is 30°C.** [emphasis added]

The specification, at page 13, lines 25-28 defines specifically hybridizes as:

The phrase "hybridizing specifically to", refers to the binding, duplexing, or hybridizing of a molecule **only to a particular nucleotide sequence** under stringent conditions when that sequence is present in a **complex mixture (e.g., total cellular) DNA or RNA.**

One of skill in the art will readily recognize that a hexamer (6 mer) will bind to a large number of sequences in a complex mixture (e.g. total cellular) DNA or RNA. Consequently the hexamers of the Boehringer Mannheim Biochemicals catalog **do not** meet all the limitations of the presently claimed invention. Accordingly, the rejection under 35 U.S.C. §102b should be withdrawn.

ICN Biomedical, Inc.

Claims 79, and 83-85 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by ICN Biomedical, Inc. (1990-91 Catalog). According to the Examiner ICN Biomedicals kits comprise containers of labeled triphosphate mixtures and the deoxyribonucleotides or ribonucleotides of these mixtures would hybridize to a nucleic acid of claim 1. Applicants traverse.

Claim 79, and consequently its dependent claims, recites:

79. A kit for the detection of a ESX gene, said kit comprising a container containing **a nucleic acid** that specifically hybridizes under stringent conditions to a nucleic acid of claim 1 wherein said stringent conditions comprise 0.01 to 1.0 M sodium ion concentration (or other salts) at pH 7.0 to 8.3 and the temperature is 30°C. [emphasis added]

The specification, at page 10, lines 25-28, states that:

The term "nucleic acid" refers to a deoxyribonucleotide or ribonucleotide polymer in either single- or double-stranded form, and unless otherwise limited, encompasses known analogs of natural nucleotides that can function in a similar manner as naturally occurring nucleotides.

Mixtures of ribonucleotides or deoxyribonucleotides triphosphates are not deoxyribonucleotide or ribonucleotide polymers. ICN Biomedical, Inc. thus fails to provide all the elements of claim 79 and dependent claims. Accordingly the rejection under 35 U.S.C. §102(b) on these grounds should be withdrawn.

Should the Examiner seek to maintain the rejections, Applicants request a telephone interview with the Examiner and the Examiner's supervisor.

If a telephone conference would expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (510) 769-3513.

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Respectfully submitted,



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